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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,517	07/03/2003	Dirk Boecker	38187-2688.US	4774
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Goodwin Procter LLP				
Attn: Patent Administrator				
135 Commonwealth Drive				
Menlo Park, CA 94025-1105				
EXAMINER				
HOEKSTRA, JEFFREY GERDEN				
ART UNIT		PAPER NUMBER		
3736				
MAIL DATE		DELIVERY MODE		
01/15/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/613,517

**Applicant(s)**

BOECKER ET AL.

**Examiner**

JEFFREY G. HOEKSTRA

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.5-18, 21-38, 50-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1.5, 6, 8-18, 21-38, 50-62 and 64-67 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Notice of Amendment*

1. In response to the amendment filed on 11/07/2008, canceled claim(s) 2-4, 19-20, 39-49, and 63 is/are acknowledged. The following is/are set forth:

### *Election/Restrictions*

2. Applicant's election of Species K, drawn to the **analyte detecting member embodiment of Figure 134** in the reply filed on 11/07/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/07/2008.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
5. For record clarity, the Examiner reiterates the analyte detecting member embodiments set forth in the Election Requirement mailed 04/01/2008 and hereinafter Set 1: "analyte detecting member" embodiments:

- Species A directed to figures 70-71;
- Species B directed to figure 72;
- Species C directed to figure 73;
- Species D directed to figure 78;
- Species E directed to figure 86;
- Species F directed to figure 88;
- Species G directed to figures 126-129;
- Species H directed to figure 130;
- Species I directed to figures 131-132;
- Species J directed to figure 133;
- Species K directed to figure 134; and
- Species L directed to figure 136.

***Election/Restrictions***

6. This application contains claims directed to the following patentably distinct sets of species:
7. Set 2: "body fluid sampling system" embodiments:
  - Species A2: embodiment drawn to a body fluid sampling system, comprising *inter alia*: a cartridge, a penetrating member driver, a plurality of penetrating members, and a plurality of analyte detecting members, and a position sensor and apparently drawn to at least claim 64;

- Species B2: embodiment drawn to a body fluid sampling system, comprising *inter alia*: a cartridge, a penetrating member driver, a plurality of penetrating members, a plurality of analyte detecting members, and a coupler engaging the penetrating member and apparently drawn to claim 65;
  - Species C2: embodiment drawn to a body fluid sampling system, comprising *inter alia*: a cartridge, a penetrating member driver, a plurality of penetrating members, a plurality of analyte detecting members, and sterility enclosure covering a tip of a penetrating member and apparently drawn to claim 66; and
  - Species D2: embodiment drawn to a body fluid sampling system, comprising *inter alia*: a cartridge, a penetrating member driver, a plurality of penetrating members, a plurality of analyte detecting members, and a user interface and apparently drawn to claim 67.
8. Set 3: "penetrating member" embodiments:
- Species A3: "an elongate member without molded attachments" embodiment apparently drawn to claim 57;
  - Species B3: "a needle having a lumen therein" embodiment apparently drawn to claim 58;
  - Species C3: "a microneedle having a lumen therein" embodiment apparently drawn to claim 59; and
  - Species D3: "a spring based device and at one of the following: a motor and gear box, a nanomuscle, pneumatic device, a liquid magnetic coil actuation device, a

stepper motor, a micro-clutch device, and an inductive motor” embodiment apparently drawn to claim 61.

9. Set 4: “penetrating member driver” embodiments:

- Species A4: “spring based” embodiment apparently drawn to claims 10; and
- Species B4: “voice coil, a rotary voice coil, a solenoid, a motor and gear box, a nanomuscle, or a combination of any of the above” embodiment apparently drawn to claim 21.

10. Set 5: “penetrating member sensor” embodiments:

- Species A5: “penetration depth information” sensor embodiment apparently drawn to claims 13-17;
- Species B5: “velocity information” sensor embodiment apparently drawn to claim 18; and
- Species C5: “a capacitive incremental encoder, an incremental encoder, an optical encoder, or interference encoder” sensor embodiment apparently drawn to claim 38.

11. Set 6: “processor utilization” embodiments:

- Species A6: “monitor position and speed of a penetrating member” embodiment apparently drawn to claims 24 and 27; and

- Species B6: “monitor an application and withdraw force” embodiment apparently drawn to claims 25 and 26.
12. Set 7: “tissue stabilizer” embodiments:
- Species A7: “application of vacuum” embodiment apparently drawn to claims 51 and 56; and
  - Species B7: “application of force” embodiment apparently drawn to claim 52.
13. Set 8: “fracturable seal” embodiments:
- Species A8: “one seal” embodiment apparently drawn to claim 53;
  - Species B8: “two seal” embodiment apparently drawn to claim 54; and
  - Species C8: “at least three seal” embodiment apparently drawn to claim 55.
14. The species in each set are independent or distinct because claims to the different species in each set recite the mutually exclusive characteristics of such species. In addition, these species in each set are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species from each set for prosecution on the merits** to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 appears generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the



prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

15. A telephone call was made to Paul Davis on 01/13/2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736